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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/729,146	12/04/2003	Timothy A. Ringeisen	KN P 0146	1356
42016	7590	06/23/2006	EXAMINER	
KENSEY NASH CORPORATION 735 PENNSYLVANIA AVENUE EXTON, PA 19341			ROGERS, JAMES WILLIAM	
			ART UNIT	PAPER NUMBER
			1618	
DATE MAILED: 06/23/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 10/729,146	Applicant(s) RINGEISEN ET AL.	
	Examiner James W. Rogers	Art Unit 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-73 is/are pending in the application.
- 4a) Of the above claim(s) 1-21, 34, 35 and 66-73 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-33 and 36-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>08/24/2005</u> . | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Election/Restrictions***

Applicant's election without traverse of Group II in the reply filed on 05/16/2006 is acknowledged. The examiner notes that the applicant did not elect a species for generic claims 55-59, therefore the examiner will elect a fibrous matrix shaped in a sheet.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 29 and 30 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clearly defined in the specification at least when searched by the examiner what is meant by the device can have an anisotropic structure (claim 30) or an isotropic structure (claim 31), the examiner does not feel these limitations are adequately defined and are therefore are unclear. In order to facilitate a shorter examination process the examiner defined anisotropic structure to mean a structure in which properties differ according to the direction of measurement, while isotropic is defined as having identical properties in all directions.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

Art Unit: 1618

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 22-33, 38-45, 47-49, 51-53 and 61-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Stone (US 5,158,574).

Stone teaches a prosthetic meniscus with one or more types of cross-linked bioabsorbable fibers, which are oriented in phosphate buffered saline solution by compressing with a rotating piston; the meniscus contains pores in which a bioactive agent (adhesion molecule) can be contained. See col 3 line 9-66, col 4 lin 16-33, col 6 lin 40-66, col 8 lin 57-64 and examples. Regarding claims 23 and 24, the limitation that the implantable device contains at least one reinforcing element is met because Stone teaches that the prosthetic can comprise a mesh, See col 4 lin 5-11. Regarding claims 43-45 the Stone patent teaches that the fibers can be formed in an oriented or random manner, see col 11 lin 18-25. Regarding claim 49 phosphates are well known plasticizers known to those skilled in the art therefore the limitation is met.

Claims 22-33, 37-48 and 51-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (US 2002/0127270).

Li teaches an oriented crosslinked bipolymeric membrane formed by compressing an aqueous solution containing the fibers and orientating the fibers by a rotating mandrel, the membrane also can contain a bioactive agent. See [0004]-[0005], [0009], [0010], [0011]-[0043], [0056], [0061]. Regarding claims 23 and 24, the limitation that the implantable device contains at least one reinforcing element is met because Li teaches that the membrane can contain a mesh, See [0051]. Regarding claim 37 the Li patent clearly states that the biopolymeric fibers possess greater mechanical strength

due to their orientation in one direction, allowing them to be sutured thus meeting the limitation that the implantable device is arranged to accept a suture and resist tearing. Regarding claims 41 and 46 Li teaches a method of fabricating multiple layer membrane (meeting the multiple plates limitation) the layers are preferably oriented in different directions, thus meeting the limitation in claim 46. See [0005], [0021]-[0042] and [0061] Regarding claims 43-45 the Li patent teaches that by controlling the angle of fiber orientation between the two layers, mechanical properties of the bilayer membrane are defined, thus it is inherent that one skilled in the art would through routine experimentation find the best orientation of the plates whether they are oriented, aligned or randomly orientated towards one another to achieve the desired properties of the film, see [0061].

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 22-33,36-48 and 51-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li et al. (US 2002/0127270). Li is disclosed above. Li is silent on the use of the membrane as a swellable hemostatic plug but it would be obvious to one skilled in the art at the time of the invention to shape the membrane to the desired dimensions of a plug and since collagen is well known to swell when exposed to water (forming gelatin), it is clearly obvious that such a device could be used as a swellable hemostatic plug.

Claim 22-33 and 36-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone (US 5,158,574) in view of Li et al. (US 2002/0127270) and in further view of Haldimann (US 6,428,576 B1).

Stone is disclosed above. Stone does not disclose a compressed fiber matrix in which the orientation of fibers within each plate is independent of the orientation of fibers within adjacent plates. Stone also does not specifically disclose that the implantable device has any special mechanical properties that would resist tearing from a suture. Stone is silent on the use of the membrane as a swellable hemostatic plug but it would be obvious to one skilled in the art at the time of the invention to shape the membrane to the desired dimensions of a plug and since collagen is well known to swell when exposed to water (forming gelatin), it is clearly obvious that such a device could be used as a swellable hemostatic plug. Lastly Stone is silent on the use of plasticizers in the fiber matrix.

Li is disclosed above. Li does disclose a method of fabricating a multiple layer membrane in which the layers are preferably oriented in different directions. Li also discloses that the biopolymeric fibers possess greater mechanical strength due to their orientation in one direction, allowing them to be sutured.

Haldiman is used primarily to show that the use of plasticizers and particulates in implantable bio-polymers was well known to the skilled artisan at the time of the invention. See abstract, col 9 lin 12-28 and example 8.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because Stone discloses all of applicants claimed invention except independent orientation of the fibers in different layers and Stone does not disclose an increase in the tear resistance of the oriented fiber while the Li patent discloses the layers are preferably oriented in different directions in order to achieve greater mechanical strength which would be resistant to tearing by suture due to its increased mechanical strength. The motivation to combine the above documents would be an oriented fibrous implant comprised of multiple plates that can be oriented at any angle to one another to achieve greater mechanical strength with the benefit of more resilience to tearing from suturing. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory

obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-26,29-30,36-38 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1,3-11,15-19 and 21-25 of copending Application No. 10/010,304.

This is a provisional obviousness-type double patenting rejection, claims 22-26,29-

30,36-38 are generic to all that is recited in claims 11,15-19 and 21-25 of U.S.

Application No. 10/010,304. That is, claims 11,15-19 and 21-25 of U.S. Application No.

10/010,304 falls entirely within the scope of claims 22-26,29-30,36-38 or in other words,

claims 22-26,29-30,36-38 are anticipated by claims 11,15-19 and 21-25 of U.S.

Application No. 10/010,304. Specifically both disclose an implantable porous polymeric material formed by compression with a lubricating agent. U.S. Application No.

10/010,304 discloses that a biological agent can be added and includes surfactants,

thus meeting the limitation of a lubricant. U.S. Application No. 10/010,304 also

discloses that the polymeric gel can be injected into a mold thus meeting the limitation



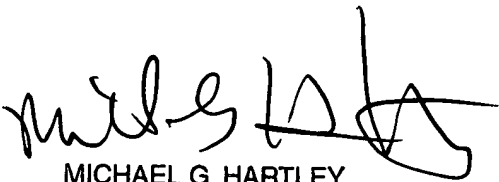
that the fibers are compressed. U.S. Application No. 10/010,304 also discloses several reinforcing elements and sutures that can be in contact with the polymer.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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